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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11 and 101

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RIN 0910-AG56

Food Labeling; Calorie Labeling of Articles of Food in Vending Machines; Extension of Compliance Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; extension of compliance date.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the compliance date for certain requirements in the final rule requiring disclosure of calorie declarations for food sold from certain vending machines. The final rule appeared in the Federal Register of December 1, 2014. We are taking this action in response to requests for an extension and for reconsideration of the rule's requirements pertaining to the size of calorie disclosures on front-of-package labeling.

DATES: Effective date: This final rule is effective December 1, 2016.

Compliance date: The compliance date for type size front-of-pack labeling requirements (§ 101.8(b)(2) (21 CFR 101.8(b)(2))) and calorie disclosure requirements (§ 101.8(c)(2)) for certain gums, mints, and roll candy products in glass-front machines in the final rule published December 1, 2014 (79 FR 71259) is extended to July 26, 2018. The compliance date for all other requirements in the final rule (79 FR 71259) remains December 1, 2016.

FOR FURTHER INFORMATION CONTACT: April Kates, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371, email: april.kates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of December 1, 2014 (79 FR 71259), we published a final rule establishing requirements for providing calorie declarations for food sold from certain vending machines. The final rule, which is codified primarily at § 101.8, will ensure that calorie information is available for certain food sold from a vending machine that does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article, or does not otherwise provide visible nutrition information at the point of purchase. The declaration of accurate and clear calorie information for food sold from vending machines will make calorie information available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices. The final rule applies to certain food from vending machines operated by a person engaged in the business of owning or operating 20 or more vending machines. Vending machine operators not subject to the rules may elect to be subject to the Federal requirements by registering with FDA.

The final rule also specifies how calories must be declared. In brief,

- Vending machine operators do not have to declare calorie information for a food if a prospective purchaser can view certain calorie information on the front of the package, in the Nutrition Facts label on the food, or in a reproduction of the Nutrition Facts label on the food subject to certain requirements, or if the vending machine operator does not own or operate 20 or more vending machines.

- Calorie declarations must be clear and conspicuous and placed prominently, and may be placed on a sign in, on, or adjacent to the vending machine, so long as the sign is in close proximity to the article of food or selection button.
- The final rule establishes type size, color, and contrast requirements for calorie declarations in or on the vending machines, and for calorie declarations on signs adjacent to the vending machines.
- The final rule establishes requirements for calorie declarations on electronic vending machines, those vending machines with only pictures or names of the food items, and those vending machines with few choices (e.g., popcorn machines).

The final rule also requires vending machine operator contact information to be displayed for enforcement purposes.

The final rule implements provisions of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(q)(5)(H)).

In the preamble to the final rule (79 FR 71259 at 71282 through 71283), we stated that all covered vending machine operators must come into compliance with the rule's requirements no later than December 1, 2016.

II. Extending the Compliance Date

A. Introduction

Since we published the final rule in the Federal Register, several trade associations have contacted us to state that the type size requirement for calorie information on the package, often referred to as “front-of-pack” or FOP labeling, presents significant technical challenges to the packaged food industry. The trade associations asked us to amend the type size requirement for

FOP labeling and to provide additional flexibility for providing calorie information for gums, mints, and roll candy (see Refs. 1 and 2).

B. Type Size Requirement for “Articles of Food Not Covered” (§ 101.8(b)(2))

With respect to FOP labeling, § 101.8(b)(2), states that articles of food sold from a vending machine are not “covered vending machine food” if the prospective purchaser can otherwise view visible nutrition information, including, at a minimum the total number of calories for the article of food as sold at the point of purchase. The visible nutrition information must appear on the food label itself, be clear and conspicuous and able to be easily read on the article of food while in the vending machine, and be in a type size at least 50 percent of the size of the largest printed matter on the label and with sufficient color and contrasting background to other print on the label to permit the perspective purchaser to clearly distinguish the information.

In the preamble to the final rule (79 FR 71259 at 71269 (see comment 16 and our response)), we discussed how FOP labeling could be a way to provide visible nutrition information for articles of food that are sold from a vending machine that are not “covered vending machine food” as interpreted by § 101.8(c). We also noted how some comments felt that the rule’s type size requirement was too large, whereas others stated that the type size would be too small (79 FR 71259 at 71269). We explained that specifying the minimum type size for calorie information on vending machine food labels will provide greater clarity for both compliance and enforcement (id.).

Since the publication of the final rule, several trade associations indicated that the type size requirement would make the calorie declaration very large on some products and would make label redesign difficult and/or not practical. They noted the existence of voluntary FOP labeling programs whereby calorie information is presented in a FOP type size that ranges from

100 to 150 percent of the size of the “net quantity of contents” statement on the principal display panel. They also asked us to align the compliance date with that for the Nutrition Facts labeling rule (81 FR 33742, May 27, 2016) so that food companies can “make all changes to their food labels, including adding FOP calorie information, at the same time” (see Ref. 2). The compliance date for the Nutrition Facts label rule is July 26, 2018, for manufacturers with \$10 million or more in annual food sales.

Consequently, with respect to § 101.8(b)(2), we have decided to extend the compliance date for certain food products sold from a glass-front vending machine that allow prospective purchasers to view packaged foods offered for sale. Specifically, if the food is:

- Sold from a glass-front vending machine that allows prospective purchasers to view packaged foods offered for sale;
- not a covered vending machine food within § 101.8(b)(2); and
- the label for such packaged foods provides front-of-package calorie disclosures that complies with all aspects of the final vending machine labeling rule except that the disclosure is not 50 percent of the size of the largest print on the label,

then the compliance date for § 101.8(b)(2) is extended to July 26, 2018. This extension of the compliance date will give us time to consider whether a revision to § 101.8(b)(2) is necessary and also give packaged food manufacturers more time to consider label redesign issues or, in the case of products without FOP calorie labeling, to consider whether to add such labeling. We emphasize that this extension is limited to vending machine operators whose glass-front vending machines are subject to § 101.8(b)(2) and where the packaged food has FOP calorie disclosures that complies with all aspects of the final vending machine labeling rule except that the disclosure is not 50 percent of the size of the largest print on the label. Thus, a vending machine

operator whose vending machines dispense packaged food without FOP labeling or use electronic displays is not affected by the extension. Similarly, a vending machine operator whose vending machines sell unpackaged food (such as fruit) is not affected by the extension.

C. Signage for Gums, Mints, and Roll Candy

With respect to providing calorie information for gums, mints, and roll candy, our regulations, at § 101.8(c), establishes requirements for calorie labeling for certain food sold from vending machines. Under § 101.8(c)(2)(i)(C), the calorie declaration for covered vending machine food must include the total calories present in the packaged food, regardless of whether the packaged food contains a single serving or multiple servings. Under § 101.8(c)(2)(ii)(A), the calorie declarations for covered vending machine food must be clear and conspicuous and placed prominently on a sign in close proximity to the article of food or selection button so long as the calorie declaration is visible at the same time as the food, its name, price, selection button, or selection number is visible.

Several trade associations have disagreed with § 101.8(c)(2) insofar as it would apply to gums, mints, and roll candy. The trade associations contend that gums, mints, and roll candy suitable for vending machines are not typically amenable to FOP labeling due to the limited size of the principal display panel, and as a result, there are few options for compliance for these products. They also describe that in glass-front vending machines, these items are often placed together at the bottom of the machine with limited space for signage. In addition, the trade associations have asserted that providing calories declarations “per serving” for these items is preferable to providing calories “per container”, because consumers typically do not consume the entire packaged product at one time, and providing calorie declarations on a “per serving” basis would be consistent with our serving size requirements at 21 CFR 101.9. The trade associations

also explained that these items typically contain insignificant amounts of all nutrients and are otherwise exempt from packaged food nutrition labeling, and that providing a sign with a range of 0 to 25 calories “per serving” for these items is sufficient for consumers to make informed choices (Ref. 1). Based on these distinct challenges, the trade associations also suggested that we amend § 101.8(c)(2) by adding a new paragraph that would, in effect, provide an exception for gums, mints, and roll candies that would allow the use of a range of calories (such as “25 calories or less/serving”) and the covered vending machine food:

- Contains at least three servings per package;
- has a “reference amount customarily consumed” (the portion size based on the amount the average person is likely to eat at one time) of 5 grams or less; and
- contains 25 calories or less per serving.

The trade associations indicated that the extension would only be for vending machine operators who, by December 1, 2016, have “interim calorie signage” that would consist of a single sign in close proximity to the article of food or selection button or inside the vending machine, where the sign states that gum, mint, and roll candies provide 25 calories or less/serving.

We addressed a similar issue in the preamble to the final rule (see 79 FR 71259 at 71276 through 71277 (see comment 24 and our response)) and explained why the calorie declaration requirement applies to the entire package rather than to a serving in the package. We disagree with the trade associations’ suggestion that the final vending machine rule’s serving size requirement should be consistent with that in our serving size rule. The vending machine rule applies to certain vending machine operators, whereas the serving size rule applies to food manufacturers. The statutory authority behind each regulation also differs; the vending machine label requirement is found in section 403(q)(5)(H) of the FD&C Act, which requires, generally,

that food sold in certain vending machines disclose the number of calories contained in food, whereas section 403(q)(1)(A)(i) of the FD&C Act requires, with certain exceptions, that food that is intended for human consumption and offered for sale bear nutrition information that provides a serving size that reflects the amount of food customarily consumed and is expressed in a common household measure that is appropriate to the food. Section 2(b)(1)(B) of the Nutrition Labeling and Education Act further requires the Secretary of Health and Human Services to issue regulations to establish standards to define serving size. Nevertheless, we note that, in the preamble to the final vending machine rule, we said we would allow, in addition to the total calorie declaration for the food as vended, the voluntary declaration of calories per serving for covered vending machine foods (see 79 FR 71259 at 71277). The voluntary declaration of calories per serving, in addition to declaration of calories per container (required by § 101.8(c)(2)), should accommodate the trade associations' desire to disclose the number of calories per serving.

However, we also are mindful that the gums, mints, and roll candies mentioned by the trade associations tend to be sold in small packages that do not lend themselves to FOP labeling and often are located or placed in a small space in glass-front vending machines; the small space may limit the size of any sign(s) that would disclose calorie information for each gum, mint, or roll candy. For example, we are aware that some glass-front vending machines may have trays that are different sizes; the tray width for bags of potato chips is larger than the tray width for a roll of mints or hard candies or for a small package of gum. The smaller tray size for gums, mints, and roll candy may make it difficult to add information, inside the vending machine, beyond the product's price and selection number. Therefore, we are extending the compliance

date for § 101.8(c)(2) to July 26, 2018, so that we may consider this issue further. This extension of the compliance date is limited to:

- Gums, mints, and roll candy sold in packages that are too small to bear FOP labeling and where the gums, mints, and roll candy are located in a small space within a glass-front vending machine that allows prospective purchasers to view packaged foods offered for sale;
- the space within the glass-front vending machine holding the gum, mints, and roll candy is so small such that it is not practicable to provide calorie information under each gum, mint, or roll candy; and
- the glass-front vending machine also does not or is not capable of providing calorie information electronically.

This limited change in the compliance date for § 101.8(c)(2) will give us time to consider issues relating to signage and vending machine design and give vending machine operators some flexibility in their disclosure of calorie information for gums, mints, and roll candies in small packages. In the interim, so consumers can make informed choices, we encourage vending machine operators to provide calorie information through a sign in close proximity to the gums, mints, and roll candy inside the vending machine that states the gums, mints, and roll candies provide “X” calories or less/serving, where X represents the value of the largest number of calories per serving for the gums, mints, and roll candies. We emphasize that this extension does not extend to other products in glass-front vending machines or glass-front vending machines that are capable of providing information electronically, nor does it extend to other types of vending machines. We also emphasize that the limited compliance date extension for § 101.8(c)(2) is intended to give vending machine operators more flexibility in providing calorie

information for gums, mints, and roll candy in glass-front vending machines where those gums, mints, and roll candy are located or placed in a small space such that it is not practicable to provide calorie information under each gum, mint, or roll candy. Our final rule already gives vending machine operators other ways to comply with the calorie disclosure requirement; for example, vending machine operators can provide calorie declarations on a sign adjacent to the vending machine (see § 101.8(c)(2)(ii)(C)).

III. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of this final rule (Ref. 3). We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule changes the compliance date for § 101.8(b)(2) and (c)(2), under the limited circumstances described in this document, from December 1, 2016, to July 26, 2018, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing

“any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

IV. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. References

The following references are on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>.

1. Letter from Karin F. R. Moore, Vice President and General Counsel, Grocery Manufacturers Association, to Susan Mayne, Ph.D., Director, Center for Food Safety and Applied Nutrition, dated March 31, 2016.

2. Letter from Karin Moore, Senior Vice President and General Counsel, Grocery Manufacturers Association, to Susan Mayne, Ph.D., Director, Center for Food Safety and Applied Nutrition, dated June 26, 2016.

3. Economics Staff, Office of Planning, Office of Policy, Planning, Legislation, and Analysis, Office of the Commissioner, Food and Drug Administration, “Food Labeling; Calorie Labeling of Articles of Food in Vending Machines; Extension of Compliance Date,” dated July 2016.

Dated: July 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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